

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of  
CHANG et al.

Serial No: 10/685,941

Filed: October 14, 2003

For: COMBINATION OF BRIMONIDINE  
AND TIMOLOL FOR TOPICAL  
OPHTHALMIC USE

Group Art Unit: 1614

Examiner: Brian S. Kwon

Confirmation No. 7685

**DECLARATION OF AN EXPERT REGARDING FACTS RELEVANT TO  
PATENTABILITY (37 C.F.R. § 1.132)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**PURPOSE OF DECLARATION**

1. This declaration is to establish evidence of patentability of one or more claims of the above referenced application.
2. The person making this declaration is an employee of Allergan, Inc, and is an expert in following the commercial success of pharmaceutical products.
3. The purpose of this declaration is to show commercial success of the claimed product.

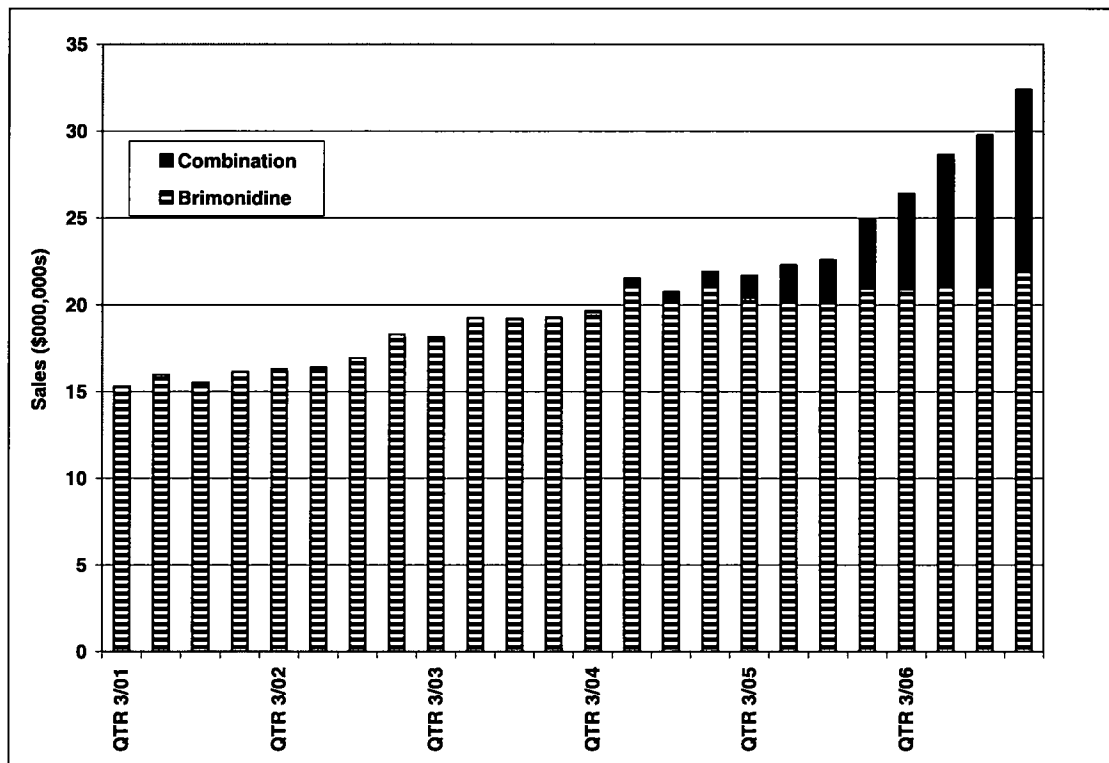
**TESTIMONY OF COMMERCIAL SUCCESS**

4. Topical ophthalmic brimonidine is available as a single drug topical ophthalmic product in the countries shown in Table 1 and in the following countries: Turkey, Egypt, Jordan, Kuwait, Lebanon, Saudi Arabia, United Arab Emirates, United States, Puerto Rico, Korea, China, Malaysia, Philippines, Singapore, and Thailand. Topical ophthalmic brimonidine has been available since at least quarter 3 of 2001 in all of these countries except Poland and Jordan, where it has been on the market since quarter 4 of 2001.
5. A topical ophthalmic product has recently been introduced which contains a combination of 0.2% brimonidine and 0.5% timolol in a single composition. Worldwide, the product has been introduced into the countries indicated in Table 1 during the quarter indicated in Table 1.

Country	Launch Quarter
Canada	Q3/03
Brazil	Q2/04
Australia	Q2/05
Switzerland	Q1/05
U.K.	Q1/05
Germany	Q4/05
Ireland	Q4/05
France	Q4/05
Mexico	Q4/05
India	Q4/05
New Zealand	Q4/05
Denmark	Q1/06
Greece	Q1/06
Argentina	Q1/06
Chile	Q1/06
Colombia	Q1/06
Czech Rep.	Q2/06
Sweden	Q2/06
Spain	Q2/06
Finland	Q3/06
Netherlands	Q3/06
Norway	Q3/06
Taiwan	Q3/06
Austria	Q4/06
Hungary	Q4/06
Poland	Q4/06
Italy	Q4/06
Belgium	Q1/07

**Table 1**

6. Figure 1 below depicts all sales (in actual dollars) of:
- a) topical ophthalmic products containing brimonidine as the sole drug ingredient in the countries of Table 1 (Brimonidine), and
  - b) a topical ophthalmic containing 0.2% brimonidine and 0.5% timolol in the countries of Table 1 (Combination),
- for the time period covering the third quarter of 2001 to the second quarter of 2007.



**Figure 1**

7. Figure 1 plainly shows that the Combination sales have steadily increased since the first launch to the present, while Brimonidine sales have been roughly constant or increased slightly.
8. Appendix 1 contains the detailed information used to generate Figure 1.
- a) Table 2 contains the raw data which includes individual country sales used to generate Figure 1.
  - b) Figure 2 plots the sales for the individual countries where the Combination has been on the market for at least six quarters.

9. Examination of the data of Appendix 1 reveals that, in each country, sales of the Combination increased steadily after launch.
10. In my expert opinion, this data is strong evidence of commercial success.
11. This data was collected during the normal course of business. Allergan's practice is to collect sales data to track the commercial success of products after they are launched.

### DECLARATION

12. As a person signing below:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

### SIGNATURE(S)

19. Person who collected data

Full name: Daryl M. Bogard, RPh, MBA  
Director, Global Marketing Information  
Allergan, Inc.

Expert's signature: \_\_\_\_\_

Country of Citizenship: USA

Residence: 19 Blessing, Irvine CA 92612

Date: September 21, 2007

**Appendix 1**

	QTR 3/03	QTR 4/03	QTR 1/04	QTR 2/04	QTR 3/04	QTR 4/04	QTR 1/05	QTR 2/05	QTR 3/05	QTR 4/05	QTR 1/06	QTR 2/06	QTR 3/06	QTR 4/06	QTR 1/07	QTR 2/07
BRAZIL				0	0	0.121	0.29	0.536	0.676	0.934	1.057	1.091	1.345	1.515	1.567	1.825
GERMANY										0	0.27	0.919	1.151	1.326	1.397	1.575
FRANCE										0	0	0.237	0.659	0.962	1.137	1.313
CANADA	0	0	0.02	0.04	0.071	0.182	0.242	0.362	0.463	0.669	0.741	0.914	0.988	1.145	1.064	1.195
SPAIN												0	0.039	0.535	0.8	0.995
MEXICO										0	0.031	0.128	0.315	0.45	0.614	0.726
ITALY														0	0.193	0.505
AUSTRALIA								0	0.053	0.168	0.179	0.239	0.29	0.349	0.306	0.368
U.K.							0	0.006	0.029	0.064	0.103	0.163	0.211	0.258	0.303	0.365
GREECE											0	0.001	0.059	0.172	0.26	0.321
CZECH REP												0	0.021	0.092	0.157	0.191
SWITZERLAND							0	0.015	0.057	0.103	0.122	0.168	0.172	0.184	0.189	0.187
INDIA										0	0.003	0.032	0.051	0.082	0.15	0.171
ARGENTINA											0	0.052	0.106	0.137	0.129	0.156
NETHERLANDS													0	0.064	0.103	0.117
COLOMBIA											0	0.034	0.037	0.063	0.081	0.106
HUNGARY														0	0.021	0.056
NEW ZEALAND										0	0.008	0.014	0.022	0.032	0.034	0.047
SWEDEN												0	0	0.014	0.026	0.034
CHILE											0	0.002	0.013	0.024	0.027	0.032
POLAND														0	0.006	0.023
IRELAND										0	0	0.007	0.014	0.017	0.017	0.02
TAIWAN													0	0.001	0.007	0.019
BELGIUM															0	0.017
FINLAND														0	0.005	0.016
DENMARK											0	0.001	0.005	0.012	0.014	0.015
NORWAY													0	0.008	0.008	0.008
AUSTRIA														0	0	0.001

**Table 2**

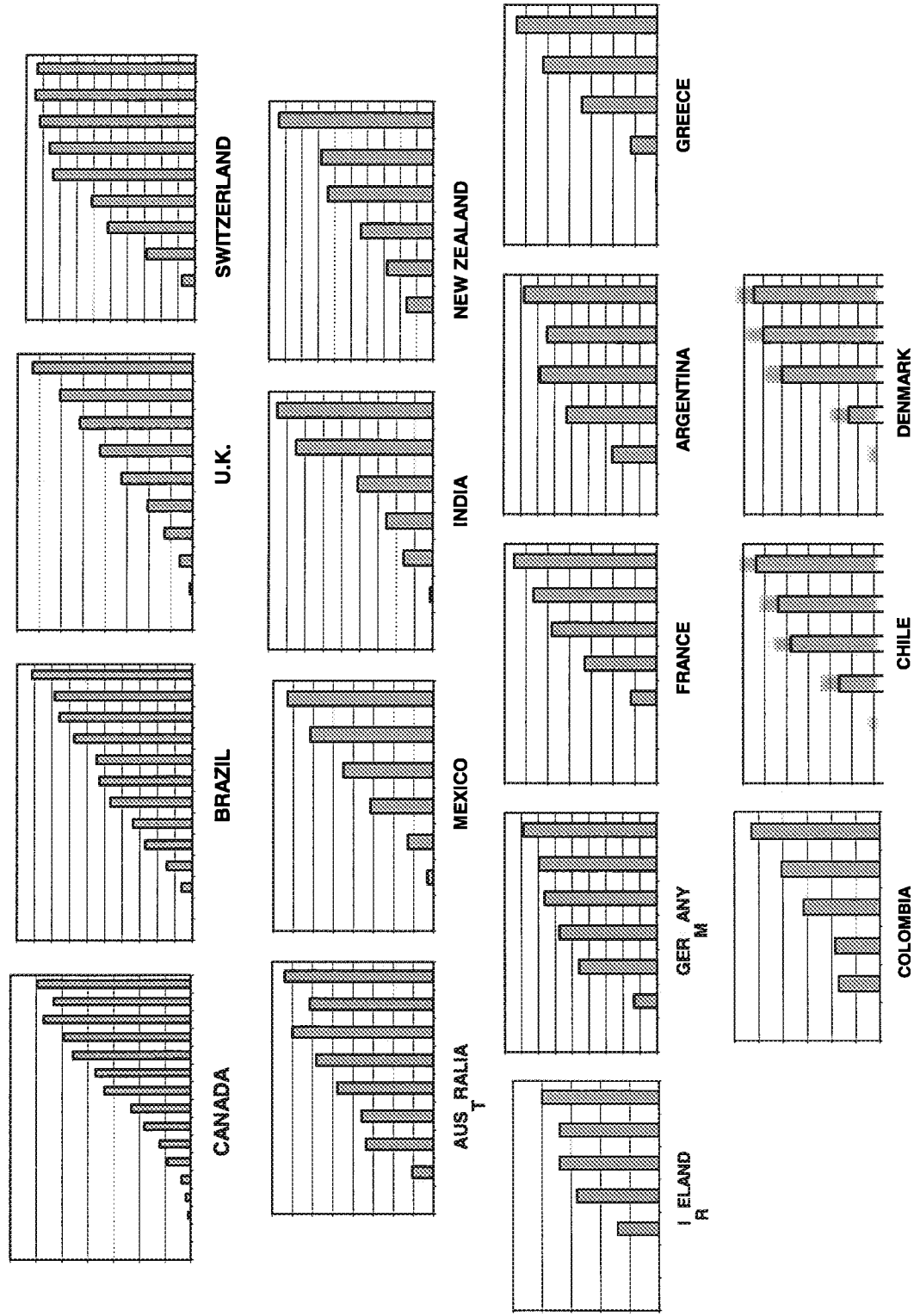


Figure 2